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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,818	03/09/2004	H. Craig Dees	0546-0203.01	2064

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EXAMINER	
SUTTON, DARRYL C	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
12/31/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/796,818	DEES ET AL.	
	Examiner	Art Unit	
	DARRYL C. SUTTON	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-7,9,10,13-15 and 17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-7,9,10,13-15 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the amendment filed 09/18/2009. No new claims have been added. Claims 8 and 16 have been canceled.

Applicant's arguments filed 09/18/2009 have been fully considered. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Rejections - 35 USC § 103

Claims 1, 5-7, 9, 10 and 13-15 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Scholz (US 5,908,619).

Applicant argues that the rejection using the prior art of Scholz is surprising since the Examiner acknowledged inadequacies of Scholz in a prior office action.

The examiner has reconsidered his original analysis and no longer believes that Scholz is inadequate. The delay in prosecution caused thereby is regretted, but is in fact legally permissible and not unusual, as long recognized by the courts:

> There is nothing unusual, certainly, about an examiner changing his viewpoint, as to patentability of claims as the prosecution of a case

> progresses, and, so long as the rules of Patent Office practice are duly complied with, an applicant has no legal ground for complaint because of such change in view. The life of a patent solicitor has always been a hard one. In re Ruschig, 154 USPQ 118, 120-21 (CCPA 1967).

Applicant argues that Scholz only refers to chlorhexidine and certain derivatives thereof, which are completely unrelated to triclosan; Scholz does not suggest or disclose that the levels of chlorhexidine can be applied to triclosan and does not provide any clue regarding an appropriate level of triclosan in the composition.

The Examiner disagrees.

Scholz teaches that other antimicrobials, i.e. a secondary antimicrobial agent, may be added to enhance the antimicrobial action of the compositions of the present invention, see page 2 of Non-final office action, dated 03/19/2009, and Scholz column 17, lines 31-35. Scholz teaches that chlorhexidine and triclosan are examples of secondary antimicrobial compounds, i.e. that they are equivalent. Since Scholz teaches that chlorhexidine is present in an amount of about 0.05%-5.0%, one of ordinary skill would contemplate the addition of its equivalent, triclosan, in those same amounts. As cited in the Non-final office action, Scholz teaches that the amount of antimicrobial should be adjusted to the minimum level which maintains a low bacteriological count, it would have been obvious for the skilled artisan to adjust the levels of triclosan around the amounts taught by Scholz to produce the required low bacteriological count and still enhance the antimicrobial agent of the composition since as Applicant has pointed out the amount of about 0.05%-5.0% is taught for chlorhexidine. Further, Scholz teaches

about 0.05%, which encompasses amounts lower than and higher than the recited value.

Applicant argues that Scholz's prescription for antimicrobial level is predicated for the lower level of the concentration on a "more is better" line of reasoning.

The Examiner disagrees.

The invention of Scholz is not only limited to the preferred embodiments, but to all of the possible embodiments disclosed in the specification. Further, as Applicant has pointed out, the amounts of secondary antimicrobial are based on chlorhexidine, which is unrelated to triclosan. Therefore, one of ordinary skill would be motivated to optimize the level of triclosan to enhance the antimicrobial action by varying the amount downward and/or upward to produce the minimum level as disclosed in Scholz; and since amounts of secondary antimicrobial are taught it would be obvious to use those amounts as a starting point for optimization.

Applicant argues that given the teachings of Scholz, it is highly unlikely that one of ordinary skill would select triclosan as an antimicrobial agent and then select a level of triclosan substantially lower than the lowest limit suggest by Scholz.

The Examiner disagrees.

The Examiner has provided responses to the selection of triclosan and to determining the amounts of triclosan above.

Applicant argues that the instant invention achieve unanticipated synergistic bactericidal activity, which is an unexpected result; and cites paragraphs [0037], [0038],

[0045], [0057] and [0060] and Tables 1 and 4 for support for the allegations of unexpected results.

The cited paragraphs and tables do not show the alleged unexpected results since the instant compositions are not compared to the closes prior art. As discussed above, Scholz teaches compositions comprised of alcohol-based violatile biocide, i.e. ethanol, isopropanol or n-propanol, and triclosan. A comparison to the compositions of Scholz would be provide a better comparison in order to determine unexpected results, particularly in the light of the teachings of Scholz that addition of triclosan at a minimum levels would enhance the antimicrobial action of the compositions.

After analyzing, even assuming *arguendo* that unexpected results have been shown, the claims would not be commensurate in scope with those showings. Applicant's compositions are only comprised of 60-70% of either ethanol or isopropanol, not all alcohols selected from the group of ethanol, isopropanol and n-propanol and not in all amounts or all amounts from greater than or equal to 30% to less than or equal to 70%; has used only 0.04% of triclosan, not all amounts between greater than 0% and equal to or less than 0.04% or all amounts between greater than or equal to 0.0001% to less than or equal to 0.04%; has only used a liquid solution, i.e. triclosan and alcohol, not an aerosol, a hydrogel or a lotion. Accordingly, the claims are much broader in scope.

Claims 1, 5-7, 9, 10 and 13-15 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Scholz (US 5,908,619) in view of Luu et al. (US 5,871,763).

Applicant argues that the is on reason that one of ordinary skill in the art would combine Scholz and Luu et al. to arrive at the instant invention. Examiner has not provided any reason why one of ordinary skill would combine the prior art, which is a clear example of improper hindsight reconstruction. Luu teaches a lotion treated substrate, and is therefore unrelated to the compositions of Scholz and it is not possible to ascertain how this might apply to a composition for direct application to the skin.

The Examiner disagrees.

As cited in the Non-final office action, Luu et al. teaches a substrate treated with a lotion, wherein the lotion contains an antibacterial agent, i.e. triclosan. Luu et al. teach that amounts of antimicrobial agents from 0.01% to about 10%, see pages 3 and 4. Further, Luu et al. teaches that the antibacterial agent will kill bacteria found on skin thereby providing enhanced cleaning and deodorizing benefit (column 4, lines 26-33). Therefore, the lotion of Luu, although intially applied to a substrate is applied directly to the skin; and the amounts of triclosan in the lotion function to kill bacteria on the skin. Since both Scholz and Luu et al. teach a lotion comprised of triclosan that is directly applied to the skin, Luu et al. provides motivation for combining with Scholz. Therefore, it would have been obvious to combine the triclosan, i.e. second antimicrobial, of Scholz in the amounts taught by Luu et al. since they are amounts known to have antimicrobial benefits.

Applicant argues that Luu et al. teaches a preference of from about 0.05% to about 5%.

The Examiner disagrees.

As discussed above, Luu et al. is not only limited to the not preferred embodiments, but contemplates all possible embodiments disclosed in the specification.

Applicant argues that Luu et al. do not teach a volatile alcohol biocide.

The Examiner disagrees.

The rejection is a 103 obviousness rejection, so Luu et al. is not required to teach each limitation, but only to provide adequate motivation for combining with the Scholz prior art. As discussed above, Luu et al. does provide adequate motivation.

Applicant argues that none of the references disclose or suggest the claimed ranges but are directed to increasing upward form the claimed range.

The Examiner disagrees.

As discussed above, Scholz teaches that the secondary antimicrobial should be at a minimum level. And as discussed above, the levels of triclosan of Luu et al. are from 0.01%-5%, it would have been obvious to optimize the antimicrobial activity of the compositions suggested by combining Scholz and Luu et al. thorough routine experimentation by varying the amount of the triclosan based on the amounts taught by Luu et al.

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is (571)270-3286. The examiner can normally be reached on M-Th from 7:30AM to 5:00PM EST or on Fr from 7:30AM to 4:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass, can be reached at (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Darryl C Sutton/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612